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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,340	01/31/2001	John T. McDevitt	5119-00524EBM	7212

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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,340

Applicant(s)

MCDEVITT ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 03, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 309-322,343 and 416-436 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 309-322,343 and 416-436 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' arguments in Paper No. 12, filed February 03, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. It is acknowledged that claims 323-342 and 375 have been cancelled.
3. Further, the addition of new claims 416-436 is acknowledged.
4. Claims herein under examination are claims 309-322, 343, and 416-436.

Information Disclosure Statement

5. It is noted that document D50, Paper 8, April 23, 2002, has been considered.
6. The information disclosure statement, Paper No.6, filed May 07, 2001, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that this instant application file lacks the documents listed on the said information disclosure statement. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1631

8. Claim 427 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is necessitated by Applicants amendment.

9. Claim 427 is rejected due to the claim being vague and indefinite. The duplication of the phrase "The system of claim 343" causes the claim to be vague and indefinite.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in:

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 309-313, 317, 318, 322, 343, 416, 418, 420-422, 428, 433, and 435 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Buechler et al. (US 6074616 A).

Applicants amending claims 309 and 343 to include the limitation of controlling operation of the analyte device from the client computer; and adding new claims 416, 418, 420-422, 428, 433, and 435 necessitate the rejection.

12. This rejection is maintained with respect to claims 309-313, 317, 318, 322, and 343 as recited in the previous office action Paper No. 11, mailed October 25, 2002. This rejection is hereby extended to newly added claims 416, 418, 420-422, 428, 433 and 435.

13. Specific to claims 309 and 343, Applicants argue that Buechler et al. does not disclose the limitations of "controlling...via the computer network" as in claim 309. Further, Buechler et

al. does not disclose a feature of "wherein...the analyte detection device from the client computer system" (pages 7-8, Paper No. 12, filed February 03, 2003). Applicants' arguments have been acknowledged and found to be unpersuasive. It is re-iterated that Buechler et al. teaches the use of a communications device to interface with an assay device for downloading test data sets, including, for example, test identifications, test instructions and calibration curves, as well as other program information and calibration and control information. Further, the method of Buechler et al. teaches that the fluorometer shares processing responsibilities, control and test data over a network with other devices such as a client computer (column 2, lines 29-44). As stated above, the capability to share program information, calibration information, control information, and test instructions between an assay device and a client computer over a network clearly anticipates the limitation of generating control signal and transmitting the control signal to an assay device to operate the device. Further, it is possible to transmit test instructions from a remote health care facility via a client computer to the assay device to perform a specific test and test results would be sent to various locations via a network (column 2, lines 44-54).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1631

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 309-322, 343, 416, 418, 420-428, 430-433, and 435 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (P/N US 6,074,616) taken with Bowman-Amuah et al. (P/N US 6,332,163 B1). Applicants amending claims 309 and 343 to include the limitation of controlling operation of the analyte device from the client computer; and adding new claims 416, 418, 420-428, 430-433, and 435 necessitate the rejection.

17. This rejection is maintained with respect to claims 314-316 and 319-321 as recited in the previous office action Paper No. 11, mailed October 25, 2002. This rejection is hereby extended to amended claim 343 and newly added claims 416, 418, 420-428, 430-433, and 435.

18. Applicants' argument that the claims are not obvious over Buechler et al. in view of Bowman-Amuah et al. has been found to be unpersuasive.

19. In response to applicant's argument that the claims are not obvious over Buechler et al. in View of Bowman-Amuah et al. pursuant to 35 U.S.C. §103(a) (Page 9, Section D), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

20. In this case, a skilled artisan would have been motivated to partake the concept emphasized by Buechler et al. for facilitating communications between the fluorometer and one or more other devices such as a computer (Column 2, Lines 29-31) as a means of collecting and transmitting chemical information from an assay device via a computer network by adding improved communications capabilities. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to add improved communications capabilities via a web server, web site or greater network availability via the intranet, extranet or LAN as described by Bowman-Amuah et al.
21. Further, Applicants' arguments that "many of the dependent claims are separately patentable over the cited art" have been acknowledged, however, found unpersuasive. Specific to claims 314, 315, 416 and 417, which are dependent from claim 309; and they are not separately patentable due to being dependent from claim 309.
22. Specific to the limitations in claims 314, 315, and 416, Applicants argue Buechler et al. and Bowman-Amuah et al. have not suggested the combinations of the limitations of the said claims with the other features of claim 309 (Page 9, Section E).
23. Applicants' arguments have been acknowledged and found to be unpersuasive. In response to applicant's argument that Buechler et al. taken with Bowman-Amuah et al. do not suggest the combinations of the limitations of the said claims with the other features of claim 309, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071,

5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

24. It is re-iterated that the limitations of claim 309 disclosed by Buechler et al. are cited in paragraph 14 of this instant action and page 3, paragraph 6 of Paper No. 11, mailed October 25, 2002. Specific to claims 314, 315, and 416, the said limitations disclosed by Bowman-Amuah et al. are cited on page 5, paragraph 11, of Paper No. 11, mailed October 25, 2002.

25. In this case, a skilled artisan would have been motivated to partake the concept emphasized by Buechler et al. for facilitating communications of optical signal between the fluorometer and one or more other devices such as a computer (Column 2, Lines 29-31) as a means of collecting and transmitting chemical information from an assay device via a computer network by adding improved communications capabilities such as a web server and a means of displaying the transmitted chemical information as taught by Bowman-Amuah et al.. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to add improved communications capabilities via a web server, web site or greater network availability via the intranet, extranet or LAN as described by Bowman-Amuah et al.

26. Claims 309, 343, 419, 429, 435, and 436 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (P/N US 6,074,616) taken with Cholli et al. (P/N US 5,985,120). Applicants amending claims 309 and 343 to include the limitation of controlling operation of the analyte device from the client computer; and adding new claims 419, 429, 435, and 436 that include the limitation of identification of analytes in a fluid system necessitate the rejection.

27. Buechler et al. teaches the limitations of claims 309 and 343 as cited above and on pages 3-4 of the previous office action Paper No. 11, mailed October 25, 2002. However, Buechler does not disclose the use of a detection device to determine the identity of the analytes in a fluid system.

28. Cholli et al. discloses a method for identifying and quantifying different components of complex analytes solutions (column 1, lines 40-42 and Figures 6-8). Further, analytes are detected by a diode array detector or any other absorbance detector capable of monitoring a single and the response from the information from the detection device is recorded by the interfaced computer system (column 8, lines 39-42), as in claims 419, 429, 435, and 436.

29. Clearly, a skilled artisan would have been motivated to partake the concept emphasized by Buechler et al. for facilitating communications between the fluorometer and one or more other devices such as a computer (Column 2, Lines 29-31) as a means of collecting and transmitting chemical information from an assay device via a computer network and improve on it by incorporating the method of Cholli et al. for rapidly identifying and quantifying different components of complex analyte solutions (column 1, lines 40-42). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to improve on the invention of Buechler et al. and add to it new rapid sensors for identifying and quantifying different components of complex analyte solutions as taught by Cholli et al.

30. Claims 309, 343, 417, and 434 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (P/N US 6,074,616) taken with Baorto et al. (1997). Applicants amending claims 309 and 343 to include the limitation of controlling operation of the analyte device from

Art Unit: 1631

the client computer; and adding new claims 417 and 434 that include the limitation of Logical Observation Identifiers Name and Code format necessitate the rejection.

31. Buechler et al. teaches the limitations of claims 309 and 343 as cited above and on pages 3-4 of the previous office action Paper No. 11, mailed October 25, 2002. However, Buechler et al. does not disclose wherein the chemical information comprises Logical Observation Identifiers Name and Code format.

32. Baorto et al. discloses the use of Logical Observation Identifiers Name and Code (LOINC) format for exchanging electronic laboratory data (abstract), as in claims 417 and 434.

33. Clearly, a skilled artisan would have been motivated to partake the concept emphasized by Buechler et al. for facilitating communications between the fluorometer and a client computer (Column 2, Lines 29-31) as a means of collecting and transmitting chemical information from an assay device via a computer network to other health facilities (column 2, lines 44-54) and improve on the invention by using a standard set of names and codes for electronic exchange of laboratory data (Abstract) as taught by Baorto et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to improve on the invention of Buechler et al. and add to it a standard set of names and codes such as LOINC for electronic exchange of laboratory data between health care facilities taught by Baorto et al.

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

35. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION

36. NO CLAIM IS ALLOWED.

37. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Application/Control Number: 09/775,340

Art Unit: 1631

Page 11

40. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
4/17/03

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER